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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/590,153  | 04/16/2007  | Rikke Stavnsbjerg    | 030427-0110         | 2481             |
| 23428 7590 02/18/2010<br>FOLEY AND LARDNER LLP<br>SUITE 500<br>3000 K STREET NW<br>WASHINGTON, DC 20007 |             |                      |                     |                  |
| EXAMINER  |             |                      |                     |                  |
| MACAULEY, SHERIDAN R  |             |                      |                     |                  |
| ART UNIT  |             | PAPER NUMBER         |                     |                  |
| 1651  |             |                      |                     |                  |
| MAIL DATE   |             | DELIVERY MODE        |                     |                  |
| 02/18/2010  |             | PAPER                |                     |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/590,153

**Applicant(s)**

STAVNSBJERG ET AL.

**Examiner**

SHERIDAN R. MACAULEY

**Art Unit**

1651

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 02 November 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 14-26 is/are pending in the application.
- 4a) Of the above claim(s) 19-24 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-18 and 25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 4/16/2007.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☒ Other: See Continuation Sheet.

Continuation of Attachment(s) 6). Other: Partial English Machine Translation of DE2805676.

### **DETAILED ACTION**

Claims 14-26 are pending.

#### ***Election/Restrictions***

1. Applicant's election without traverse of claims 14-18 and 25 and trehalose and *Lactobacillus* spp. as the species of additives and LAB, respectively, in the reply filed on November 2, 2009 is acknowledged. The requirement for restriction/election is deemed proper and is therefore made final.
2. Claims 19-24 and 26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions and species, there being no allowable generic or linking claim.
3. Claims 14-18 and 25, insofar as they read upon the elected species, are examined in this office action.

#### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:  

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. Claims 14-18 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
6. Claim 14 and its dependents are rendered indefinite by the recitation of "with the exception of a frozen lactic acid bacteria (LAB) culture that comprises ... and wherein

the culture comprises cryoprotective agent ..." at the last five lines of claim 14. It is unclear whether applicant intends for the claim to recite that the exception is only the LAB culture recited after "with the exception" or whether applicant intends for the claim to recite that the exception is also when the culture comprises the cryoprotective agents recited thereafter. If applicant intends the latter, it is recommended that applicant pluralize "exception", if applicant intends the former, it is recommended that the two terms be separated by a line break.

7. It is further unclear in claim 14 how applicant intends for the items following the term "with the exception of" to be an exception. Applicant could intend to recite that, if the LAB are able to utilize sucrose, then the cryoprotective agents recited thereafter are utilized; that LAB that are able to utilize sucrose are excluded from the LAB that are useful in the composition; or some other alternative.

8. Claim 16 is rendered indefinite by the recitation of "selected from the group comprising". The use of the term "comprising" instead of "consisting of" results in an improper Markush style claim. Alternative expressions are permitted only if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. The term "selected from the group comprising" renders the claim indefinite because it is unclear what is and is not included in the group recited thereafter. See MPEP 2173.05(h).

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

10. Claims 14-18 and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Bisgaard-Frantzen et al. (WO 2004/065584 A1; reference cited in IDS).

11. The applied reference has common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

12. The claims recite a pellet-frozen lactic acid bacteria (LAB) culture in a commercially relevant package that has a weight of at least 50 g frozen material,

wherein the frozen material is present in the form of individual pellets, having a content of viable bacteria of at least  $10^9$  colony forming units (CFU) per g frozen material and comprising from 0.5% to 13% of an additive compound measured as w/w of the frozen material, wherein the additive compound is an additive compound that is trehalose, and which further is characterized by, when using an amount of 10% of the additive compound measured as w/w of the frozen material, the compound is able to increase the  $T_m'$  (onset temperature of ice melting) of the frozen lactic acid bacteria (LAB) culture, which without the additive compound has a  $T_m'$  value from -70 degrees C to -46 degrees C, to a  $T_m'$  value above -46 degrees C, such as from -45 degrees C to -15 degrees C.(measured by DSC) and wherein the frozen lactic acid bacteria (LAB) culture is characterized by that when stored at approximately -46 degrees C for 7-14 days the individual pellets of the frozen culture are not sticking together and therefore substantially remain as individual pellets where this is measured by following test the individual pellets of the frozen culture are pellet frozen in liquid nitrogen and 100 individual pellets (around 5-100 g of pellets) are poured into a petridish, thus forming a thin layer of loose individual single pellets, the layer being characterized in that the majority of the pellets are in physically contact with one or more of its neighbor pellets, placed at approximately -46 degrees C for 7-14 days and examined to see if the pellets are still loose or if the pellets had made clumps or are sticking together wherein the criteria for that the individual pellets of the frozen culture substantially remain as individual pellets are that at least 80 of the 100 individual pellets remain as loose individual single pellets; with the exception of a frozen lactic acid bacteria (LAB) culture

that comprises LAB that are able to utilize sucrose and wherein the culture comprises cryoprotective agent compound selected from the group consisting of sucrose in an amount from 2% to 13% of sucrose measured as w/w of the frozen material; and trehalose in an amount from 4% to 6% of trehalose measured as w/w of the frozen material; and a trehalose/sucrose mixture both in the amount of 13% measured as w/w of the frozen material. The claims further recite that the culture is a mixed mesophilic culture consisting of mesophilic bacteria having optimum growth temperatures at about 30 degrees C, and wherein the LAB is *Lactobacillus* spp. The claims also recite that the frozen lactic acid bacteria (LAB) culture is a culture which without comprising the additive compound has a T<sub>m</sub>' value of from -70 degrees C to -46 degrees C, and that the frozen lactic acid bacteria culture comprises from 5% to 10% of the additive compound measured as w/w of the frozen material. The claims also recite a pellet-frozen lactic acid bacteria (LAB) culture obtainable by the method for making a frozen lactic acid bacteria (LAB) culture of the claims.

13. The reference teaches LAB, including mesophilic bacteria and *Lactobacillus* spp., that are pellet frozen in individual pellets having a content of viable bacteria of at least 10<sup>9</sup> CFU per g frozen material and comprising 5 to 10% of an additive, such as trehalose (abstract, p. 11, lines 10-13, 29-32, p. 12, lines 14-18, p. 13, line 25-p. 14, line 4). The reference teaches that they may be packaged in commercially relevant packaging that has a weight of at least 50 g frozen material (p. 10, lines 15-31). The reference teaches that the compositions comprise all of the features recited in the claims; and any such features that are not recited by the reference would be inherently



possessed by the prior art composition. The claims recite a composition and method in terms of a function, property or characteristic. The composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference.

14. Therefore, the reference anticipates all of the limitations of the claims.

***Claim Rejections - 35 USC § 103***

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

18. Claims 14-18 and 25 rejected under 35 U.S.C. 103(a) as being unpatentable over Kringelum et al. (WO 00/39281; reference cited in IDS) in view of Jespersen (reference cited in IDS; see attached partial machine translation). The claims recite a pellet-frozen lactic acid bacteria (LAB) culture in a commercially relevant package that has a weight of at least 50 g frozen material, wherein the frozen material is present in the form of individual pellets, having a content of viable bacteria of at least 10<sup>sup.9</sup> colony forming units (CFU) per g frozen material and comprising from 0.5% to 13% of an additive compound measured as w/w of the frozen material, wherein the additive compound is an additive compound that is trehalose, and which further is characterized by, when using an amount of 10% of the additive compound measured as w/w of the frozen material, the compound is able to increase the T<sub>m</sub>' (onset temperature of ice melting) of the frozen lactic acid bacteria (LAB) culture, which without the additive compound has a T<sub>m</sub>' value from -70 degrees C to -46 degrees C, to a T<sub>m</sub>' value above -46 degrees C, such as from -45 degrees C to -15 degrees C.(measured by DSC) and wherein the frozen lactic acid bacteria (LAB) culture is characterized by that when stored at approximately -46 degrees C for 7-14 days the individual pellets of the frozen culture are not sticking together and therefore substantially remain as individual pellets where this is measured by following test the individual pellets of the frozen culture are pellet frozen in liquid nitrogen and 100 individual pellets (around 5-100 g of pellets) are poured into a petridish, thus forming a thin layer of loose individual single pellets, the

layer being characterized in that the majority of the pellets are in physically contact with one or more of its neighbor pellets, placed at approximately -46 degrees C for 7-14 days and examined to see if the pellets are still loose or if the pellets had made clumps or are sticking together wherein the criteria for that the individual pellets of the frozen culture substantially remain as individual pellets are that at least 80 of the 100 individual pellets remain as loose individual single pellets; with the exception of a frozen lactic acid bacteria (LAB) culture that comprises LAB that are able to utilize sucrose and wherein the culture comprises cryoprotective agent compound selected from the group consisting of sucrose in an amount from 2% to 13% of sucrose measured as w/w of the frozen material; and trehalose in an amount from 4% to 6% of trehalose measured as w/w of the frozen material; and a trehalose/sucrose mixture both in the amount of 13% measured as w/w of the frozen material. The claims further recite that the culture is a mixed mesophilic culture consisting of mesophilic bacteria having optimum growth temperatures at about 30 degrees C, and wherein the LAB is *Lactobacillus* spp. The claims also recite that the frozen lactic acid bacteria (LAB) culture is a culture which without comprising the additive compound has a Tm' value of from -70 degrees C to -46 degrees C, and that the frozen lactic acid bacteria culture comprises from 5% to 10% of the additive compound measured as w/w of the frozen material. The claims also recite a pellet-frozen lactic acid bacteria (LAB) culture obtainable by the method for making a frozen lactic acid bacteria (LAB) culture of the claims.

19. Kringelum teaches frozen and liquid cultures of LAB, such as mesophilic bacteria and *Lactobacillus* spp., wherein the frozen material is present at amounts up to 10<sup>12</sup>

CFU per mL (abstract, p. 1, lines 29-35, p. 6, lines 6-10, p. 8, lines 1-25). The reference teaches that up to 90% of the bacteria may be viable (p. 9, lines 24-34); thus, the amount of bacteria recited in the claims would be present in the composition of Kringelum. The reference teaches that the composition may comprise additives such as trehalose and that such additives may be present at 5%, for example (p. 4, lines 15-18, p. 7, lines 15-29). The reference does not teach all of the properties of the compositions recited in the claims, but it appears that, since the compositions possess nearly the same components, that they would inherently possess the claimed characteristics, or that the claimed characteristics could be achieved in the course of routine experimentation. The claims recite a composition and method in terms of a function, property or characteristic. The composition of the prior art appears to be the same as that of the claim but the function is not explicitly disclosed by the reference. Once rationale is provided to show that the claimed invention appears to be the same or similar to that of the prior art, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product (MPEP § 2112). Kringelum does not specifically teach that the frozen cultures are in a pellet or in the specified packaging.

20. Jespersen teaches methods of freezing liquid products, such as microbial cultures, into liquid drops or pellets (see partial English translation, attached, p. 1). The reference teaches that it is well-known in the laboratory to prepare such pellets and methods of preparing the products at an industrial or commercially relevant scale (see partial English translation, pp. 1-2). Although Kringelum does not teach pellet-frozen

bacterial cultures, one of ordinary skill in the art would be motivated to modify the teachings recited therein with the teachings of Jespersen to arrive at pellet-frozen LAB cultures because Kringelum teaches that any known method of freezing the culture may be used (p. 8, lines 8-12) and Jespersen teaches that the method is compatible with any bacterial culture (see partial English translation, p. 1). One of ordinary skill in the art would therefore have been able to select, with a reasonable expectation of success, a known method for freezing a bacterial culture, such as that of Jespersen, for use with the claimed invention. One of ordinary skill in the art would further have been able to arrive at the claimed packaging because both Kringelum and Jespersen are directed to the production of commercial products, and could therefore have arrived at the claimed packaged product in the course of routine experimentation. It would therefore have been obvious to one of ordinary skill in the art to combine the teachings discussed above to arrive at the claimed invention.

21. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

### ***Double Patenting***

22. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

23. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

24. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

25. Claims 14-18 and 25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6, 9, 13, 16 and 20-23 of copending Application No. 10/543240. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application recite nearly all of the features recited in the claims of the instant application. Those features that are not recited in the claims of the copending application are rendered obvious the claims of the instant application because they copending application clearly sets forth in the specification that the composition claimed in the copending application possesses the characteristics of the composition recited in the instant claims. Thus, the claims of the instant application are rendered obvious in view of the claims of the copending application.

26. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### **Conclusion**

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHERIDAN R. MACAULEY whose telephone number is (571)270-3056. The examiner can normally be reached on Mon-Thurs, 7:30AM-5:00PM EST, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SRM

/Ruth A. Davis/

Primary Examiner, Art Unit 1651